

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

UNITED FOOD & COMMERCIAL
WORKERS UNION AND MIDWEST
HEALTH BENEFITS FUND, on its own
behalf and on behalf of all others similarly
situated,
Plaintiff,

v.

ABBVIE INC., a Delaware corporation,
ABBOTT LABORATORIES, an Illinois
corporation, BARR PHARMACEUTICALS
INC., a Delaware corporation, DURAMED
PHARMACEUTICALS INC. (now known as
TEVA WOMEN'S HEALTH INC.), a
Delaware corporation, DURAMED
PHARMACEUTICALS SALES CORP., a
Delaware corporation, TEVA
PHARMACEUTICALS USA, INC., a
Delaware corporation, and TEVA
PHARMACEUTICAL INDUSTRIES
LIMITED, an Israeli corporation,
Defendants.

COMPLAINT – CLASS ACTION

DEMAND FOR JURY TRIAL

Plaintiff United Food & Commercial Workers Union and Midwest Health Benefits Fund (“UFCW”), on behalf of itself and all others similarly situated, for its Class Action Complaint against Defendants AbbVie Inc. (“AbbVie”), Abbott Laboratories (“Abbott”), Barr Pharmaceuticals Inc. (“Barr”), Duramed Pharmaceuticals Inc. (“Duramed”), Duramed Pharmaceuticals Sales Corp. (“DPSC”), Teva Pharmaceuticals USA, Inc. (“Teva USA”), and Teva Pharmaceuticals Industries Limited (“Teva”) (collectively, “Defendants”), alleges as follows based on (a) personal knowledge of those matters relating to itself, (b) the investigation of counsel, including the review of publicly available pleadings, court orders, and other filings concerning the conduct at issue in this action, and (c) information and belief.

I. INTRODUCTION

1. Plaintiff brings this antitrust action on behalf of a Class of end-payors that indirectly purchased or reimbursed for extended-release niacin, which is sold by AbbVie (and was sold previously by Abbott and Kos Pharmaceuticals, Inc. (“Kos”)) under the brand name Niaspan. Niaspan is the only extended-release version of niacin approved as a once-a-day prescription therapy for treating mixed lipid disorders. Plaintiff seeks to recover overcharge damages and other relief as a result of the harm incurred by the Class due to Defendants’ anticompetitive conduct, which has prevented any less expensive generic equivalent of Niaspan from entering the market. Defendants’ anticompetitive scheme is a violation of federal and state antitrust laws, state consumer protection and deceptive business practices laws, and state unjust enrichment laws.

2. The anticompetitive course of conduct described in this Complaint was set in motion by two companies -- Kos and Barr. Niaspan was Kos’ most important product,

comprising nearly two-thirds of Kos' annual sales. When Barr sought regulatory approval to launch a generic equivalent of Niaspan, Kos sued Barr, alleging various patent infringement claims. By March of 2005, Barr was prepared and poised to launch its extended-release niacin product immediately upon receiving final approval from the FDA. In order to delay the drastic loss of Kos' profits from Niaspan that would have occurred immediately upon Barr's launch, Kos and Barr reached an eleventh-hour, unlawful market allocation agreement pursuant to which Kos agreed to pay millions of dollars to Barr over the next eight years in exchange for Barr's continuing commitment not to sell an extended-release niacin product in competition with Niaspan (the "Exclusion Payment Agreement" or "Agreement"). Specifically:

- a. Kos agreed to pay Barr tens of millions of dollars in exchange for Barr's commitment to postpone competing with a generic equivalent of Niaspan until September 20, 2013;
- b. Kos' payments to Barr included lump sum amounts (which Kos paid in 2005) and quarterly payments that have been made so long as Barr delayed launching its generic equivalent of Niaspan (that is, Kos, Abbott and AbbVie have been making those payments on a quarterly basis ever since 2005);
- c. Kos and Barr cloaked their payments behind a spurious supply agreement and an equally spurious promotion agreement, but Kos' payments to Barr far exceeded the value that Barr provided, and Kos' real purpose for making the payments was to induce Barr to refrain from competing with Kos;

- d. In 2006, Abbott bought Kos, and Abbott continued to make payments to Barr (and its successor) in exchange for Barr continuing to delay competing with Niaspan, under the Exclusion Payment Agreement;
- e. In 2008, Teva bought Barr, and Teva has continued to receive payments from Abbott (and its successor) and has continued to delay competing with its generic equivalent of Niaspan, under the Exclusion Payment Agreement; and
- f. In 2013, Abbott spun off its prescription drug business to AbbVie, and AbbVie has continued to make payments to Teva in exchange for Teva continuing to delay competing with its generic equivalent of Niaspan, under the Exclusion Payment Agreement.

3. Moreover, Defendants knew and intended that the Exclusion Payment Agreement would also prevent other generic companies from launching their own generic Niaspan before Barr/Teva did, thereby creating a bottleneck. As the first filer of an Abbreviated New Drug Application (“ANDA”) for a generic equivalent of Niaspan, Barr/Teva is entitled to market its generic Niaspan for 180 days free from competition from other generic products. The parties’ Exclusion Payment Agreement can block any other generic Niaspan products from coming to market until 180 days after September 20, 2013, because the FDA will not approve any subsequently-filed ANDAs until the first-filer’s exclusivity period has run, which will not occur until 180 days after Teva launches. Abbott has also engaged in various acts and practices, described below, to prevent any other generic company from dislodging the FDA approval bottleneck created by the Exclusion Payment Agreement.

4. Defendants' scheme has worked as planned. Barr and Teva have, in fact, delayed marketing a less-expensive generic equivalent of Niaspan. But for the Exclusion Payment Agreement, a generic extended-release niacin product would have been available to Plaintiff and the Class in early 2005. Thus, absent the unlawful Exclusion Payment Agreement, Plaintiff and the members of the Class would have paid less for their prescription drug purchases. Because of Defendants' scheme to delay generic competition for Niaspan, Plaintiff and the Class have paid hundreds of millions of dollars more for Niaspan than they would have paid for their prescription drugs absent such conduct. At all times, the Defendants have shared in the illicit profits that have resulted from the artificially-inflated prices for Niaspan.

5. Defendants' unlawful Exclusion Payment Agreement was designed to and in fact did: (a) preclude the entry of less expensive generic equivalents of Niaspan in the United States; and (b) fix, raise, maintain or stabilize the price of extended-release niacin products, above the levels that would have otherwise existed if there had been competition.

6. Plaintiff brings this action on its own behalf and as a class action on behalf of all consumers and third-party payors (collectively "Class") who purchased or paid for Niaspan, other than for re-sale, since April 12, 2005 (see Class Definition below). Plaintiff seeks a judgment declaring that the Exclusion Payment Agreement, as further described below, is unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff also seeks an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26. Unless enjoined, Defendants' unlawful conduct will continue unchecked and Plaintiff and the Class will continue to bear the financial brunt of Defendants' antitrust violations. Plaintiff also asserts claims for compensatory

and/or treble damages and equitable relief for continuing violations of the State laws enumerated below.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, there are more than one hundred members of the Class, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants.

8. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

9. This Court has jurisdiction over the Defendants because they are present in the United States, they do business in the United States, they have registered agents in the United States, they may be found in the United States, and/or they are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

10. Venue is appropriate within this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this District, and because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. Moreover, one of the Defendants has a facility in this District, and another Defendant is headquartered in this District.

III. PARTIES

11. Plaintiff UFCW is an “employee welfare benefit plan.” UFCW’s office responsible for covering medical benefits, including benefits for prescription drugs, is located in Cook County, Illinois. During the Class Period, as defined below, UFCW purchased and/or provided reimbursement for brand Niaspan in Florida, Iowa, Illinois, Michigan and Missouri. UFCW paid more than it would have absent Defendants’ unlawful scheme to prevent and delay generic entry.

12. Defendant Abbott is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott purchased Kos in a tender offer transaction in 2006. On or about on January 1, 2013, Abbott spun off most of its pharmaceuticals operations to AbbVie. At all relevant times, Defendant Abbott sold Niaspan and engaged in the conduct challenged in this case and attributed to Abbott, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

13. Defendant AbbVie is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. As of January 1, 2013, Abbott spun off most of its pharmaceuticals operations to AbbVie. At all relevant times, Defendant AbbVie sold Niaspan and engaged in the conduct challenged in this case and attributed to AbbVie, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

14. Defendant Barr is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Prior to 2004, Barr was known as Barr Laboratories, Inc. In 2008, Barr became a wholly-owned subsidiary of Teva. At all relevant times, Defendant Barr engaged in the conduct challenged in this case and attributed to Barr, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

15. Defendant Duramed is a corporation organized under the laws of the state of Delaware, with principal places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva. Duramed is now known as Teva Womens Health Inc. At all relevant times, Defendant Duramed engaged in the conduct challenged in this case and attributed to Duramed, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

16. Defendant DPSC is a corporation organized under the laws of the state of Delaware, with principal places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, DPSC was a subsidiary of Barr. In 2008, when Teva purchased Barr, DPSC became a subsidiary of Teva. At all relevant times, Defendant DPSC engaged in the conduct challenged in this case and attributed to DPSC, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

17. Defendant Teva is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva is a leading manufacturer of generic drugs, and it is one of the largest sellers of generic drugs in the United States. Teva purchased Barr in 2008, and Barr is now a wholly-owned subsidiary of Teva. Teva has a facility in this District. At all relevant times, Defendant Teva engaged in the conduct challenged in this case and attributed to Teva, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

18. Defendant Teva USA is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Teva USA manufactures and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of Defendant Teva. At all relevant times, Defendant Teva USA engaged in the conduct challenged in this case and attributed to Teva USA, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

19. Although not named as Defendant, Kos was one of the initiators of the unlawful scheme described in this Complaint. Kos was a corporation organized under the laws of the state of Florida, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. In 2006, Kos was merged into and became a part of Abbott, which became the successor to all of Kos' unlawful conduct described in this Complaint.

20. Although not named as Defendant, Kos Life Sciences, Inc. was one of the initiators of the unlawful scheme described in this Complaint. Kos Life Sciences Inc. was a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. Kos Life Sciences Inc. was a wholly-owned subsidiary of Kos. In 2006, when Kos was merged into Abbott, Kos Life Sciences Inc. became a Division of Abbott Laboratories, and Abbott became the successor to all of Kos Life Sciences Inc.'s unlawful conduct described in this Complaint.

21. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the illegal restraint of trade alleged herein, and were authorized, ordered, and/or performed by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

IV. REGULATORY BACKGROUND – GENERIC DRUG APPROVAL PROCESS

A. Generic Drugs Benefit Purchasers.

22. Generic competition enables purchasers, at all levels of the pharmaceutical supply chain, to (a) purchase generic equivalents of the brand name drug at a substantially lower price than the brand name drug, and (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, insurers, pharmacies, and other drug purchasers.

23. Orally available generic solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for approval, are assigned an "AB" rating by the United States Food & Drug

Administration (“FDA”). The “AB” rating permits the generic drug to be substituted for the brand name drug at the pharmacy counter.

24. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written. Until a generic manufacturer enters the market, no substitution can occur, and the brand name manufacturer can therefore charge supracompetitive prices profitably without material loss of sales volume to generics. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the market entry of generic competition.

25. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. In addition, many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts’ sales, causing a significant reduction of the branded drug’s unit and dollar sales.

26. Typically, the first AB-rated generic drug is priced significantly below its branded counterpart. Upon the entry of additional AB-rated generics, also priced much less than their branded counterparts, drug prices generally decline, falling further over time, as more generic equivalents compete with each other.

27. Once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often capturing 80% or more of the market within the first six months. About

one year after market entry, the generic often takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product.

28. Brand manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible -- including illegal means.

B. The FDA Oversees New Drug Approvals And Allows Manufacturers To List, But Does Not Check The Validity Of, Applicable Patents Covering Their Products In The Orange Book.

29. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must apply for FDA approval to sell the new drug by filing a New Drug Application ("NDA"). *21 U.S.C. §§ 301-392*. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. *Id. at §§ 355(a) & (b)*.

30. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic equivalent of the brand name drug) in the FDA's "Orange Book," or book of Approved Drug Products with Therapeutic Equivalence Evaluations. *21 U.S.C. §§ 355 (b)(1) and (c)(2)*. New patents obtained after NDA approval must be listed in the Orange Book as related to the NDA if the new patent claims either the approved drug (for compound patents) or approved methods of use for the approved drug (for method-of-use patents). The NDA holder is required to file information on any such patent with the FDA within thirty days of the patent's issuance. *21 U.S.C. §§ 355 (b)(1) and (c)(2)*.

C. The Federal Government Encourages And Facilitates The Approval Of Generic Drugs Through The Hatch-Waxman Amendments.

31. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments to the FDCA, changed the approval standards for generic drugs. (*See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).*) Through the Hatch-Waxman Amendments, Congress sought to expedite the market entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

32. A generic manufacturer seeking approval to sell a generic equivalent of a brand name drug may file an Abbreviated New Drug Application ("ANDA"). If an ANDA applicant shows that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is "bioequivalent" to the brand name drug – then the ANDA may rely on the scientific safety and effectiveness findings included in the brand name drug manufacturer's original NDA. The FDA assigns an "AB" rating to generic drugs that are bioequivalent to branded drugs.

33. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products are therapeutically equivalent and may be substituted for one another when the products: (1) contain identical amounts of the same active ingredients in the same route of administration and dosage form; (2) meet applicable standards of strength, quality, purity and identity; (3) are manufactured in compliance with current good manufacturing practices regulations; and (4) are adequately labeled. Bioequivalence demonstrates that the active

ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. *21 U.S.C. § 355(j)(8)(B)*.

1. Generic Drugs Must Be Bioequivalent To Their Branded Counterparts.

34. The Hatch-Waxman Amendments created section 505(j) of the FDCA and established the current ANDA approval process. *21 U.S.C. § 355(j)*. To obtain approval, an ANDA applicant is not required to submit evidence on the clinical safety and effectiveness of the drug product; instead, an ANDA relies on the FDA's previous finding that the reference listed drug (or "RLD," the brand drug) is safe and effective. To rely on a previous finding of safety and effectiveness, an ANDA applicant must demonstrate, among other things, that its drug product is bioequivalent to the RLD. *21 U.S.C. § 355(j)(2)(A)(iv)*. In addition, an ANDA must contain, with certain exceptions not relevant here, information to show that the proposed drug has the same active ingredient(s), indications of use, route of administration, dosage form, strength, and labeling as the RLD. *21 U.S.C. §§ 355(j)(2)(A), (j)(4)*. The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements delineated in § 505(j)(2)(A) of the Act, including a demonstration of bioequivalence. *21 U.S.C. § 355(j)(4)*.

2. Generic Companies Must Certify That Their Product Will Not Infringe The Patents Listed In The Orange Book.

35. To obtain FDA approval, an ANDA applicant must provide one of several certifications to the FDA and the patent holder regarding patents and other exclusivities covering the brand product. First, the generic manufacturer must certify that the generic drug will not infringe patents covering the drug, as listed in the Orange Book, because (I) no patents exist on the brand product; (II) any listed patents will have expired by the time the product comes to market; (III) the generic product will not come to market until the listed patents expire; or (IV)

the listed patents are invalid or will not be infringed by the sale of the generic product. *21 U.S.C. § 355(j)(2)(A)(vii)(I-IV)*. The last certification, that the patents are invalid or not infringed, is known as a “Paragraph IV Certification.”

36. If a generic manufacturer files a Paragraph IV certification, it constitutes a technical act of infringement under the Hatch-Waxman Amendments -- even though the generic product is not yet on the market. If the brand manufacturer sues within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of: (a) the passage of thirty months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer’s ANDA. The FDA may grant “Tentative Approval,” but cannot authorize the generic manufacturer to go to market before the passage of thirty months or a court decision of invalidity or non-infringement.

37. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic equivalents of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, *i.e.*, all generics (other than one marketed by the branded manufacturer) are kept off the market for at least six months. For ANDAs with Paragraph IV certifications filed before December, 2003, a first-filer’s 180-day exclusivity period will only be triggered upon the earlier of (a) the first-filer’s commercial launch, or (b) entry of a final judgment from a court decision of invalidity, unenforceability, or non-infringement. That is, the FDA will not approve any subsequently-filed ANDA until the first-

filer's 180-day exclusivity period has run, which (absent a final judgment on a relevant court decision) will not occur until 180 days after the first-filer launches its product.

D. This Regulatory Scheme Is Susceptible To Abuse Through Anticompetitive Settlement Agreements.

38. Brand companies have learned how to exploit this regulatory scheme to prolong generic entry beyond lawful limits. This section describes, in general terms, how the regulatory features are ripe for abuse, and how such abuse can delay generic competition. That these features can be, and have been, abused does not mean that Congress, the FDA, or the Court system sanctions this manipulation.

39. Although not intended to do so, the FDA statutes and regulations provide incentives for brand manufacturers to “settle” infringement suits by paying the first filed generic to stay off the market, thus (i) withdrawing that competitive threat from the market, and (ii) “bottlenecking” approval for other would-be generic competitors. A drug patent settlement in which the brand company pays the generic company to drop a patent challenge has anticompetitive effects, including delayed generic competition, and artificial life extension for invalid patents. Because the first filed generic is entitled to six months of market exclusivity (as to other generics), some agreements push off the entry date of the first generic filer, which can block all other generics from coming to market for at least as long as the market exclusivity period lasts. The brand benefits by holding on to its monopoly for longer and the generic benefits from the compensation while still retaining its own period of exclusivity. But purchasers suffer by not having access to more affordable generic drugs.

40. Although not intended to do so, the FDA statutes and regulations provide incentives for parties to delay or avoid the formal settlement of their patent infringement

litigation. Since the FDA is prohibited from approving a generic until the earlier of thirty months or a court decision on infringement and invalidity, both parties have an incentive to resolve the dispute on anticompetitive terms without formally settling or dismissing the litigation.

V. FACTS

A. Niaspan Accounts For the Vast Majority of Kos' Sales Revenues.

41. Niacin, the active ingredient in Niaspan, is Vitamin B-3. It was discovered in the late 1800s, appears naturally in many foods, and started being sold as a dietary supplement in the United States no later than the 1930s. In proper dosages, niacin will raise levels of HDL cholesterol (the so-called “good” cholesterol) in patients. However, at high levels, niacin causes a patient’s skin to flush with redness, and it may cause liver toxicity.

42. In the 1990s, Kos set out to develop a time-release version of niacin, which could avoid the side effects associated with high dosages of niacin, and which could be marketed as a once-a-day therapy to boost HDL cholesterol in patients who needed treatment for cholesterol levels. Eventually, Kos developed Niaspan, a time-release version of niacin, which it intended to market as a brand name prescription drug. Importantly, Kos did not claim to have discovered that niacin reduces cholesterol (that was documented in the 1950s), and was not the first company to make a sustained release niacin formulation. Kos simply created a formulation that had a release rate that helped minimize or avoid certain side effects.

43. Kos was unable to patent the active ingredient in Niaspan under a compound patent, because niacin was not an innovative chemical compound. However, Kos sought and eventually received a series of patents to cover the formulation and method-of-use for Niaspan. Those patents were as follows:

Patent No. 6,080,428 (the '428 Patent)
Patent No. 6,129,930 (the '930 Patent)
Patent No. 6,406,715 (the '715 Patent)
Patent No. 6,469,035 (the '035 Patent)
Patent No. 6,676,967 (the '967 Patent)
Patent No. 6,746,691 (the '691 Patent)
Patent No. 6,818,229 (the '229 Patent)

In addition, Kos purchased Patent Nos. 5,126,145 and 5,268,181 (the '145 Patent and the '181 Patent).

44. Kos filed an NDA with respect to Niaspan, and on July 28, 1997, Kos received FDA approval to market Niaspan for the treatment of mixed lipid disorders.

45. Over time, Kos submitted the above-listed patents to FDA for listing in the Orange Book, and the FDA listed them in the Orange Book.

46. In September of 1997, Kos went to market with Niaspan, eventually selling Niaspan in dosages of 500 mg, 750 mg, and 1000 mg. Niaspan was the only once-a-day prescription formulation of extended release niacin available for treating mixed lipid disorders. Because of its unique position, doctors prescribed Niaspan often, and the drug quickly became a multi-million dollar seller.

47. In the early years, nearly all of Kos' Sales Revenue was derived from sales of Niacin, because Kos had no other significant drugs in its portfolio. As the years progressed, Kos began to sell other drugs, but Niaspan always accounted for substantial portion of Kos' Sales Revenues. Specifically, in those early years:

- a. In 2001, Kos sold \$87 million of Niaspan, which accounted for 100% of the company's Sales Revenue.

- b. In 2002, Kos sold \$146 million of Niaspan, which accounted for 84% of the company's Sales Revenue.
- c. In 2003, Kos sold \$226 million of Niaspan, which accounted for 77% of the company's Sales Revenue.
- d. In 2004, Kos sold \$319 million of Niaspan, which accounted for 64% of the company's Sales Revenue.
- e. In 2005, Kos sold \$435 million of Niaspan, which accounted for 57% of the company's Sales Revenue.

48. In the early part of the 2000s, Kos had market power with respect to pricing Niaspan. Indeed, on several occasions during those early years, Kos reported that it was able to raise prices on Niaspan (even though costs were not increasing) while simultaneously increasing its sales volumes on the drug.

B. Barr Seeks FDA Approval to Market a Generic Equivalent to Niaspan, And Kos Views Barr as a Competitive Threat.

49. On October 2, 2001, after conducting extensive research and analysis regarding the patents that Kos had registered, after conducting extensive legal due diligence concerning potential infringement or invalidity of Kos's patents, and after investing more than \$2.3 million on that research, Barr submitted ANDA 76-250 to the FDA, seeking approval to market a generic equivalent of the 1000 mg dosage of Niaspan.

50. On January 15, 2002, Barr sent a Paragraph IV Certification with respect to the listed patents covering Niaspan in a 1000 mg dosage. In that Paragraph IV Certification, Barr stated that its proposed generic equivalent to Niaspan would not infringe any of Kos' patents then listed in the Orange Book, that Kos' patents were invalid, and/or that Kos' patents were

unenforceable. Barr was the only company to file such a certification at that time. That Paragraph IV Certification marked the beginning of Barr's efforts to bring a generic equivalent of Niaspan to market. As the first ANDA filer, Barr expected that it would someday have an exclusive 180-day period to market its generic equivalent of Niaspan.

51. Kos immediately saw Barr as a competitive threat, and sought to thwart Barr's efforts to bring a generic equivalent of Niaspan to market. President and CEO Adrian Adams promised that Kos would "vigorously enforce [its] patent rights in order to protect Kos's cholesterol products, which [Kos has] effectively pioneered entirely on [its] own."

52. On March 4, 2002, Kos sued Barr in the United States District Court for the Southern District of New York (docketed as 02-CV-1683), alleging that Barr's Paragraph IV certification infringed upon the '428 Patent and the '930 Patent with respect to the 1000 mg dosage of Niaspan. By operation of law, the filing of that lawsuit triggered a 30-month stay that prohibited the FDA from granting Barr Final Approval to launch a generic equivalent of Niaspan.

53. In the months that followed, Kos filed two more patent infringement lawsuits against Barr with respect to patents relating to Niaspan.

- a. On August 13, 2002, Kos filed a patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-CV-6409), this time alleging that Barr had infringed the '428 Patent and '930 Patent by filing ANDA 76-738 (with an accompanying a Paragraph IV Certification) with respect to the 500 mg and 750 mg dosages of Niaspan.

- b. On November 12, 2002, Kos filed a patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-CV-8995), this time alleging that Barr had infringed the '715 Patent by submitting a Supplemental Paragraph IV Certification (dated September 30, 2002) regarding Niaspan.

These lawsuits were all consolidated into one proceeding. Under the law as it existed at that time, each of those lawsuits triggered a new 30-month stay, and the last of those 30-month stays began to run on September 30, 2002 (the date of Barr's Supplemental Paragraph IV Certification).

Thus, the FDA was stayed from granting Barr Final Approval for marketing any generic equivalent of Niaspan until March 31, 2005. (Congress amended the relevant statute in 2003, and no lawsuit filed after 2003 would result in a new 30-month stay with respect to the approval of Barr's ANDAs and its proposed generic equivalent of Niaspan.)

54. On March 26, 2004, Kos filed a fourth patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 04-CV-1683), this time alleging that Barr had infringed the '967 Patent by filing Paragraph IV Certifications with respect to Niaspan.

55. That fourth case was consolidated with the first three cases, into one single proceeding. In the consolidated proceeding, Barr filed Counterclaims against Kos, seeking Declaratory Judgments that Barr's Paragraph IV Certifications did not infringe any of the relevant patents held by Kos (specifically naming the '145 Patent, the '181 Patent, the '428 Patent, the '715 Patent and the '930 Patent). Barr's Counterclaims also sought rulings that those patents were invalid or otherwise unenforceable.

56. On September 3, 2004, Barr filed an action against Kos in the United States District Court for the Southern District of New York (docketed as 04-CV-7086), seeking a Declaratory Judgment that Barr was not infringing the ‘691 Patent and/or that the ‘691 Patent was invalid or otherwise unenforceable. This fifth lawsuit was also consolidated with the other pending patent infringement actions in New York.

57. While the patent suits were pending in New York, and while the 30-month stay was still in place from the first three lawsuits, the FDA gave Barr Tentative Approval to proceed to market with its generic equivalent of Niaspan. Barr received tentative approval to market its 1000 mg generic equivalent of Niaspan on May 9, 2003 and received tentative approval to market its 500 mg and 750 mg generic equivalents of Niaspan on June 13, 2003. Barr expected to receive final approval from the FDA shortly after the last of the 30-month stays expired (that is, shortly after March 31, 2005). (In this Complaint, unless indicated otherwise, “Niaspan” refers to all of the dosages of the drug.)

58. The patent lawsuits in New York continued for more than two years without any substantive rulings on the merits of the patent claims. There were no claims construction rulings and no summary judgment rulings. On December 3, 2004, the Court scheduled a Trial for the consolidated cases for January of 2006.

C. Barr Is Ready to Launch a Generic Equivalent of Niaspan At-Risk in The Spring of 2005.

59. As 2004 was drawing to a close, Barr was preparing to launch its generic equivalent of Niaspan shortly after the 30-month stay expired, but before the patent litigation was resolved. (In the pharmaceutical industry, a generic launch before the resolution of the patent infringement litigation is called an “At-Risk” launch.) By Spring 2005, Barr was ready

and willing, and would have been able, to launch its generic equivalent to Niaspan as soon as the FDA approved Barr's ANDA.

60. Barr's At-Risk launch would have brought a generic to market in the Spring of 2005, without regard for the strength of the claims in the pending patent lawsuits, and without regard to the expiration dates on any of Kos' patents (as listed in ¶ 41, above). Kos recognized Barr's At-Risk launch as a real competitive threat and acted swiftly in response.

- a. First, Kos began preparing to launch its own authorized generic version of Niaspan, which would have deprived Barr of 180 days of exclusivity as the sole generic on the market, and which would have replaced some of Kos's lost brand revenues with those from authorized generic purchases. Kos began manufacturing its authorized generic version of Niaspan so that it would have inventory on hand to sell as soon as Barr launched. By the end of the first quarter of 2005, Kos had accumulated more than \$1.3 million in inventory for its authorized generic launch. Kos was prepared to launch -- and would have launched -- an authorized generic version of Niaspan in early 2005, if Barr had launched its generic equivalent of Niaspan At-Risk.
- b. Second, on March 7, 2005, Kos filed papers with the New York Court in the patent litigation, applying for a preliminary injunction to prohibit Barr from continuing with its At-Risk launch of a generic equivalent of Niaspan. The Court held a hearing on Kos' application for a preliminary injunction on March 18, 2005. At the time of the March 18th Hearing on Kos' Application for a Preliminary Injunction, Barr was ready to launch its generic equivalent of Niaspan, At-Risk.

Barr was accumulating inventory that it would need to fill orders for its generic product as soon as the launch occurred. Barr was only waiting on the FDA to issue Final Approval, which Barr expected to receive in April.

D. Kos and Barr Enter the Exclusion Payment Agreement, Agreeing That Barr Will Not Launch A Generic Competitor to Niaspan For More Than Eight Years.

61. On March 30, 2005 -- before the New York Court ruled on Kos' application for a preliminary injunction -- Kos and Barr announced that they had settled the patent litigation, and they asked the court to postpone any ruling on that application, so that they could formalize their settlement. The Judge agreed, and issued a Conditional Order of Discontinuance on March 30, 2005.

62. The fact that Barr was ready to launch At-Risk -- and was going to do so in April of 2005 -- was the single most important fact that led Kos to settle the patent litigation in March of 2005. Because Niaspan was so important to Kos' viability, and because the prospect of an At-Risk launch by Barr posed too great a threat to the pricing of Niaspan, Kos needed a way to prevent generic entry so that it could continue to charge higher prices and continue to sell a large volume of Niaspan.

63. Thus, Kos and Barr entered into the Exclusion Payment Agreement: Kos agreed to make unlawful payments to Barr over a period of eight years, and Barr unlawfully agreed to refrain from launching a generic equivalent of Niaspan until September of 2013. That Agreement preserved Niaspan's dominant position in the market, while sharing some of the extraordinary revenues that were the result of that dominant position.

64. As part of the Exclusion Payment Agreement, on April 12, 2005, Kos and Barr executed three contracts that facilitated and helped effectuate their unlawful Agreement. Those three contracts were as follows:

- a. **Settlement and License Agreement.** Kos and Barr agreed to drop all claims and counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license of all of the patents arguably covering Niaspan (as listed in ¶ 41, above), on the condition that Barr will not bring a generic equivalent of Niaspan to market until September 20, 2013 (or such earlier time as may be required to preserve Barr's right to market a generic exclusively for 180 days). The license also permitted Barr to launch a generic equivalent of another drug, Advicor (a drug that combined Niaspan with a Statin, a separate chemical entity that tended to lower LDL cholesterol in patients), and Barr agreed not to launch that generic until September 20, 2013. (Advicor had not been part of their patent litigation up until then.) For a period of years after Barr began selling generic Niaspan and Advicor, for every unit of generic Niacin and Advicor that Barr would sell, Barr agreed to pay a percentage of its profits to Kos. Barr explicitly agreed that it would not launch a generic equivalent of Niaspan until the date provided in the license (scheduled for September 20, 2013). Kos also agreed that it would not an authorized generic version of Niaspan.
- b. **Co-Promotion Agreement.** For as long as Barr kept its generic equivalent of Niaspan and Advicor off the market, as provided in the Settlement and Licensing Agreement, Kos agreed to pay Barr (through Duramed and DPSC, two Barr

subsidiaries), a royalty on all of Kos' sales of Niaspan and Advicor. Barr, Duramed and DPSC agreed to promote Niaspan and Advicor to obstetricians, gynecologists and other doctors specializing in women's health. The royalty that Kos paid to Barr was based upon overall sales of Niaspan and Advicor, regardless of whether the sales were made by Barr's sales force.

- c. **License and Manufacturing Agreement.** Kos (and its subsidiary, Kos Life Sciences Inc.) made a non-refundable lump-sum payment to Barr, ostensibly as compensation for Barr's investment in developing FDA-approved manufacturing processes for Niaspan and Advicor. Kos (and Kos Life Sciences Inc.) also agreed to make quarterly payments to Barr for every quarter that Barr remained ready to manufacturer Niaspan and Advicor. Barr agreed to serve as a ready back-up supplier to Kos for those products, and agreed to sell them to Kos at an agreed-upon contract price. If Barr sold a generic equivalent of Niaspan to any third-party before September 20, 2013, Kos would have no further obligation to make quarterly payments to Barr.
65. The Exclusion Payment Agreement included two other notable provisions:
 - a. Kos and Barr agreed to do all things reasonably necessary to further the intent and purposes of the transactions contemplated by the Agreement.
 - b. Kos and Barr agreed that either company could transfer its rights and obligations to a successor entity through a merger or other corporate takeover.
 66. On April 12, 2005, the New York court dismissed all of the patent infringement cases that were pending between Barr and Kos regarding Niaspan.

67. Under the Exclusion Payment Agreement, Kos has paid Barr to not launch until 2013. That payment has taken at least the following forms:

- a. A lump sum payment, which was disguised a “stand-by” payments to compensate Barr for being ready to manufacture Niaspan under the License and Manufacturing Agreement (when in fact the stand-by payment far exceeded the value that Barr provided to Kos by being ready to manufacture and supply Niaspan);
- b. Quarterly payments, which have been disguised as payments to compensate Barr for remaining ready to manufacture Niaspan under the License and Manufacturing Agreement (when in fact the quarterly payments have far exceeded the value that Barr has provided by remaining ready to manufacture and supply Niaspan);
- c. Quarterly Royalty Payments, which have been disguised as compensation for Barr’s work under the Co-Promotion Agreement (when in fact those payments have far exceeded the value of the promotion efforts that Barr has provided); and
- d. A license to begin selling a generic equivalent of Advicor, with that license beginning in 2013. Because of those payments, Barr did not launch At-Risk in April of 2005. In the years that have followed, Barr (and its successor) has continued to receive those payments, and Barr (and its successor) has continued with its commitment that it will not launch a generic equivalent of Niaspan.

68. But for the parties’ ongoing adherence to their Exclusion Payment Agreement, generic competition for Niaspan would have occurred earlier and prices for Niaspan (both generic and branded) would have been lower. Specifically:

- a. If Barr had launched a generic equivalent of Niaspan -- either in an At-Risk launch in April of 2005 or at any time thereafter -- the generic equivalent would have sold at lower prices than the prices at which Kos was selling the brand name version of Niaspan. Plaintiff would have paid lower prices -- on both brand name Niaspan and on the generic equivalent of Niaspan -- than it otherwise paid.
- b. If Kos had launched its authorized generic equivalent of Niaspan in 2005 -- or at any time thereafter -- prices would have dropped even lower. As a matter of pharmaceutical economics, prices fall most dramatically when two or more generic equivalents of a drug are on the market alongside a branded product. The Exclusion Payment Agreement prevented that generic competition from occurring.
- c. If Barr had launched At-Risk in April of 2005, other generic manufacturers would have been able to launch their own generic equivalents of Niaspan after 180 days had passed after Barr's At-Risk launch. That is, as the first filer, Barr had a 180-day period in which it would be the exclusive outside generic manufacturer of a Niaspan equivalent, and that 180-day exclusivity period would not begin to run until 180 days after Barr launched its product. By delaying Barr's launch until September 20, 2013, Kos and Barr sought to prevent -- and succeeded in preventing -- other generic manufacturers from launching until 2014.

69. Hence, the purpose and effect of the agreement between Kos and Barr was to suppress generic competition and to allow Kos to charge higher prices for Niaspan.

70. Kos' payments to Barr under this agreement have involved substantial sums.

- a. In 2005, Kos paid an “upfront fee” to Barr for Barr’s commitment to stand by as an alternate supply source for the Kos branded product. This fee is believed to be in the ballpark of \$5 million, which was to be supplemented with future “stand ready” quarterly fees.
- b. In 2006, Kos paid Barr \$45 million in royalty payments based on Kos’ sales of Niaspan and Advicor, which was the “maximum annual royalty” for calendar year 2006.
- c. In 2007, Kos paid Barr another \$37.0 million, which was the maximum annual royalties for that year under their co-promotion agreement for the sales of Niaspan and Advicor. Similar payments were made in subsequent years.
- d. Kos gave Barr a license to sell a generic equivalent of another product -- Advicor -- and an opportunity to earn royalties on Kos’ sales of Advicor prior to that generic entry, even though Advicor had not been a part of the patent dispute that was being settled. Because Kos included Advicor in the Exclusion Payment Agreement, Kos paid Barr millions of dollars more than it otherwise would have paid.
- e. Kos (and its successors) has continued to pay Barr (and its successor) throughout the unlawful and ongoing Agreement, and those payments have involved tens of millions of dollars every year. Those payments are still occurring in 2013.

71. Consistent with their unlawful Agreement, Kos and Barr took steps to conceal their unlawful conduct.

- a. In the Spring of 2005, both companies repeatedly stated that the effect of the agreement was to bring a generic equivalent of Niaspan to the market in 2013, which they asserted was four years earlier than the expiration date of the last-expiring Kos Patent. These statements were misleading -- and both companies knew that they were misleading -- because those statements ignored the fact that Barr would have launched a generic equivalent of Niaspan At-Risk in April of 2005. Thus, when Kos and Barr proclaimed that their settlement would bring generic equivalents of Niaspan to market sooner than they otherwise would have arrived, both companies knew that the real purpose and effect of their unlawful Agreement was to delay generic entry for more than eight years.
- b. In the Spring of 2005, Kos and Barr both refused to disclose the amount of the payments that Kos would provide to Barr, because they had agreed to conceal the amounts of the payments that Barr was receiving. Repeatedly, when Wall Street analysts asked either company to disclose the amounts of the payments (or even the details for how the amounts would be calculated), the companies refused.
- c. Kos filed copies of contracts dated April 12, 2005 with the Securities and Exchange Commission as part of its 10-Q filing dated August 9, 2005, but the publicly-filed versions of those contracts redacted the financial terms regarding the payments. Neither company reported the amounts of the payments as separate items in their financial reports. Additionally, the publicly-filed versions of the contracts contained recital clauses that falsely stated that the parties were

hastening the entry of a generic equivalent of Niaspan, when in fact the parties had agreed to delay generic entry for more than eight years.

72. In the Spring of 2005, Barr disposed of its inventory that it had accumulated to be ready for its generic launch, and Barr took an inventory write-down in connection with its decision not to launch At-Risk in April of 2005. Also, in the Spring of 2005, Kos took a write-down for its generic inventory of a generic version of Niaspan. (Kos had accumulated that inventory through the First Quarter of 2005, on the expectation that Kos would need to begin selling a generic product as soon as Barr launched At-Risk).

E. Abbott Acquires Kos And Continues the Unlawful Agreement to Suppress Generic Competition.

73. In November of 2006, Abbott proposed to acquire control of Kos through a tender offer transaction. Abbott offered to pay Kos shareholders \$78 per share, which represented a 56% premium on the open market share price of \$50 per share. At the time that Abbott made that offer, Kos' portfolio of products was still heavily dependent on Niaspan, and Kos did not have very many products in development. Thus, Niaspan (along with the above-described unlawful and ongoing Exclusion Payment Agreement that was keeping Barr from launching a generic equivalent of Niaspan) was a central element of Abbott's valuation of Kos' business.

74. Abbott's tender offer was successful, and Kos was merged into Abbott in December of 2006. As Kos' successor, Abbott stepped into the shoes of Kos with respect to the ongoing unlawful Exclusion Payment Agreement with Barr. Barr continued to refrain from entering the market with a generic equivalent of Niaspan, agreeing to hold off until the agreed upon launch date on September 20, 2013, and Abbott continued to make the agreed-upon

payments to Barr. In this way, both parties continued with the unlawful Exclusion Payment Agreement, suppressing generic competition for Niaspan.

75. Upon the completion of the merger, Abbott joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for Niaspan. Abbott did not withdraw from that conspiracy, and instead continued to participate in it.

76. To the extent that the Exclusion Payment Agreement had any minimal lawful value to Kos in the form of co-promotion services or backup supply arrangements, those considerations had even less value to Abbott, because Abbott was large enough to have its own promotion and supply capacity. The Exclusion Payment Agreement was valuable to Abbott because the Agreement was postponing Barr's launch of a generic equivalent of Niaspan, and Abbott was willing to continue to pay Barr for that ongoing suppression of generic competition.

77. Because Abbott was a substantially larger enterprise than Kos was, Abbott was better able to exploit the market advantages created by the ongoing unlawful agreement to suppress generic competition. After Abbott took over the Niaspan business, sales of Niaspan increased significantly. Over the years, U.S. retail sales of Niaspan grew as follows:

2006	\$ 474 million
2007	\$ 546 million
2008	\$ 639 million
2009	\$ 717 million
2010	\$ 794 million
2011	\$ 1.13 billion
2012	\$ 1.03 billion

F. Teva Acquires Barr and Continues the Unlawful Agreement to Suppress Generic Competition.

78. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva continued to follow the unlawful Exclusion Payment Agreement that was then in place with Abbott. Teva continued to refrain from entering the market with a generic equivalent of Niaspan, agreeing to hold off until September 20, 2013, and Abbott continued to make the agreed-upon payments to Teva.

79. As a result of its acquisition of Barr, Teva also owned (either directly or indirectly) the first-filer rights held by Barr. Accordingly, no other generic company will be able to could launch a generic equivalent of Niaspan until Teva has had a 180-day period as the exclusive generic seller. Assuming that Teva launches a generic equivalent of Niaspan on September 20, 2013, no other generic company can introduce a generic equivalent of Niaspan until March of 2014.

80. Upon the completion of its acquisition of Barr, Teva joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for Niaspan. Teva did not withdraw from that conspiracy, and instead continued to participate in it.

G. Abbott Acts to Preserve the Unlawful Agreement to Suppress Generic Competition.

81. In furtherance of the unlawful and ongoing Exclusion Payment Agreement with Teva, Abbott took additional steps to ensure that nothing happened to disrupt the agreement that Teva would not launch its generic until September of 2013.

82. For example, Abbott knew that if any other generic drug manufacturer obtained a final judgment following a court decision of invalidity, unenforceability or non-infringement, then Teva would be forced to launch its generic product immediately, because Teva's 180-day exclusivity period would begin to run. Such a final judgment on Abbott's patent rights would force Teva to enter the market before the agreed-upon launch dated of September 20, 2013, and Defendants' unlawful scheme would have been cut short. Defendant recognized this risk, and Abbott undertook to avoid such a disruption. Specifically:

- a. On March 6, 2009, Abbott filed a patent infringement lawsuit against Lupin Limited in the United States District Court for Delaware (docketed as 09-CV-152). Abbott alleged that Lupin, a generic manufacturer, had infringed Abbott's patent by filing a Paragraph IV Certification as part of an effort to launch a generic equivalent of Niaspan. On June 13, 2012, Abbott and Lupin stipulated to a dismissal of the lawsuit. The Delaware Court never ruled on whether Lupin had infringed Abbott's patents, and there was never a final judgment on Lupin's claims that Abbott's patents were invalid or unenforceable.
- b. Over the next three years, Abbott filed several more patent infringement lawsuits against generic manufacturers who had filed Paragraph IV Certifications with respect to a possible generic equivalent of Niaspan. *Abbott Laboratories v. Sun Pharmaceuticals Indus. Ltd.* (D. Del. Dkt. No. 10-CV-112); *Abbott Laboratories v. Sandoz, Inc.* (D. Del. Dkt. No. 10-CV-538); *Abbott Laboratories v. Cadila Healthcare Ltd.* (D. Del. Dkt. No. 12-CV-0065); *Abbott Laboratories v. Amnael Pharmaceuticals LLC* (D. Del Dkt. No. 12-CV-235); *Abbott Laboratories v.*

Mylan, Inc. (D. Del. Dkt. No. 12-CV-257); *Abbott Laboratories v. Watson Laboratories, Inc.* (D. Del. Dkt. No. 12-CV-324); *Abbott Laboratories v. Kremers Urban Pharmaceuticals, Inc.* (D. Del. 12-CV-703); *Abbott Laboratories v. Amnael Pharmaceuticals LLC* (D. Del. Dkt. No. 12-CV-1088); and *Abbott Laboratories v. Watson Laboratories, Inc.* (D. Del. 12-CV-1409). Three of those cases have been dismissed by stipulation, with no final judgments entered on the infringement, the validity or the enforceability of Abbott's patents. The other four cases remain pending, and are still in the early stages of discovery, with no final judgments entered on the infringement, the validity, or the enforceability of Abbott's patents.

In all of these lawsuits, Abbott has been able to avoid the entry of any definitive ruling that would disrupt the trigger date for the 180-day exclusivity for Teva. Through delay, and through settlements, Abbott has ensured that no final judgment has been entered on non-infringement, invalidity or unenforceability of the relevant patents.

83. Abbott has prosecuted these patent cases as part of its agreement to take steps that are necessary to preserve the agreement to suppress generic competition, as part of the Exclusion Payment Agreement. Abbott's dilatory conduct in these lawsuits was -- and is -- part of and in furtherance of its ongoing unlawful Agreement with Teva to suppress generic competition in the market for Niaspan.

H. Abbott Spins Off Niaspan to AbbVie, and AbbVie Continues With the Unlawful Agreement to Suppress Generic Competition.

84. In 2012, Abbott announced that it was spinning off most of its prescription drug business into a new company, AbbVie. That spin-off became effective as of January 1, 2013. As

Abbott's successor, AbbVie has stepped into the shoes of Abbott with respect to the ongoing unlawful Agreement with Teva. Teva has continued to refrain from launching a generic equivalent of Niaspan, and AbbVie has continued to make the agreed-upon payments to Teva.

85. Upon the transition of the Niaspan business from Abbott to AbbVie (which occurred on or about on January 1, 2013), AbbVie joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for Niaspan. AbbVie did not withdraw from that conspiracy, and instead continued to participate in it.

I. The Unlawful Agreement to Suppress Generic Competition is Ongoing, and It Continues to Cause Injury.

86. As of today, no generic equivalent of Niaspan or Advicor is on the market in the United States. AbbVie continues to sell brand name Niaspan and Advicor at artificially-inflated prices, and Plaintiff has been denied the lower prices that generic competition would have brought to the market. This lack of generic competition is the direct result of the ongoing unlawful Agreement that began in 2005, has continued ever since then, and will continue at least through the end of 2013.

87. The unlawful agreement will result in higher prices in another way. In September of 2013, when Teva begins selling generic Niaspan, Teva will charge higher prices than would have been charged but for the Exclusion Payment Agreement, because Teva has an agreement with AbbVie that both companies will share the profits from Teva's sales of a generic equivalent of Niaspan. To allow for that profit sharing, Teva will launch its generic at a higher price than it otherwise would have.

88. During the four-year period prior to the filing of this Complaint, the Defendants' unlawful conduct has been ongoing and the Plaintiff has continued to suffer injury every day that the Defendants' unlawful Agreement not to compete has remained in place. During the applicable limitations period, the Defendants have operated under an ongoing Agreement to suppress generic competition, and Plaintiff has been injured by the Defendants' conduct.

J. The Unlawful Agreement to Suppress Generic Competition Harms Competition, Injures the Plaintiff, and Causes Damages.

89. As of May 9, 2003, Barr's ANDA for a generic equivalent of the 1000 mg dosage of Niaspan ANDA was in approvable condition, and the FDA issued its Tentative Approval then. As of June 13, 2003, Barr's ANDA for a generic equivalent of the 500 mg and 750 mg dosages of Niaspan was in approvable condition, and the FDA issued its Tentative Approval then. That is, the FDA issues Tentative Approval only when it determines that an ANDA would otherwise be ready for final approval but for a 30-month stay.

90. But for Defendants' overarching, anticompetitive and ongoing scheme to delay generic Niaspan competition in the United States, a generic equivalent of Niaspan would have been available in the United States far earlier than September 20, 2013 (which is the first date that a generic product is likely to become available). But for the anticompetitive, illegal and ongoing conduct described in this Complaint, a generic equivalent of Niaspan would have been available as early as April of 2005 (when Barr received Final Approval from the FDA to market its generic equivalent, and when Barr would have launched its generic product At-Risk).

91. Additionally, but for the illegal conduct described in the Complaint, Kos would have launched its own authorized generic Niaspan product in early 2005, resulting in additional price competition for Niaspan.

92. Alternatively, but for the substantial payments Kos made to Barr in exchange for Barr's agreement to delay marketing its generic equivalent to Niaspan until September 20, 2013, Kos and Barr would have agreed to a licensed entry date significantly earlier than September 20, 2013. Without the payments, which were the *quid pro quo* for the delay, Barr would have reached Agreement on an earlier licensed entry.

93. But for the anticompetitive, illegal and ongoing conduct alleged in this Complaint, Plaintiff and members of the Class would have begun to pay less for their Niaspan requirements long ago. As a result, Defendants, by their conduct, have injured Plaintiff and the Class by causing them to pay substantial overcharges -- potentially hundreds of millions of dollars -- on their purchases of Niaspan.

VI. MARKET CHARACTERISITICS

94. At all relevant times, Kos, Abbott and AbbVie had the power to maintain the price of Niaspan products (meaning Niaspan in all its dosage strengths) at supracompetitive levels without losing substantial sales to other products.

95. A small but significant, non-transitory price increase for Niaspan would not have caused a significant loss of sales so as to make the higher prices unprofitable.

96. Niaspan does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than an AB-rated generic equivalent of Niaspan (which has never entered the market).

97. Because of, among other reasons, its unique profile as a once-a-day Niacin therapy for treating mixed lipid disorders, Niaspan is differentiated from all products other than AB-rated generic equivalents of Niaspan (which have never entered the market).

98. Kos, Abbott, and AbbVie needed to control only Niaspan (and any AB-rated generic equivalents for Niaspan), and no other products, in order to maintain the price of Niaspan profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic equivalent of Niaspan would render Kos, Abbott, and AbbVie unable to profitably maintain supracompetitive prices of Niaspan without losing substantial sales.

99. Kos, Abbott and AbbVie also sold branded Niaspan at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

100. Defendants have had, and exercised, the power to exclude generic competition to branded Niaspan.

101. Defendants, at all relevant times, enjoyed high barriers to entry with respect to the market for Niaspan products.

102. To the extent that Plaintiff is legally required to define a relevant product market, Plaintiff alleges that the relevant market is all Niaspan products -- *i.e.*, Niaspan (in all its dosage strengths) and AB-rated bioequivalent products. During the period relevant to this case, Defendants have been able to profitably maintain the price of Niaspan well above competitive levels.

103. The relevant geographic market is the United States and its territories.

104. At all relevant times, Kos, Abbott, and AbbVie has had a 100% market share in the relevant market, and will continue to have that market share until September 20, 2013. For the period from September 20, 2013 until March of 2014, the Defendants will share a 100% market share in the relevant market.

VII. MARKET EFFECTS

105. Kos began to ship Niaspan to Plaintiff and other members of the Class on or shortly after July 28, 1997, after receiving the FDA's formal, written final approval of its NDA. No generic equivalent of Niaspan has ever been available for sale in the United States.

106. Defendants' anticompetitive scheme had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Niaspan from generic competition. But for the unlawful Exclusion Payment Agreement, Barr would have entered the market with a generic equivalent of Niaspan as early as April of 2005 (when Barr received Final Approval from the FDA to do so), and one or more generic equivalents of Niaspan would have been on the market at all times since then. The Defendants' unlawful scheme allowed Kos (and later Abbott and AbbVie) to exclude competition in the market for Niaspan products, leading to higher prices paid by Plaintiff and all other members of the Class.

107. But for the Defendants' overarching anticompetitive scheme, Kos would have launched an authorized generic in April of 2005, to compete with Barr as soon as Barr launched At-Risk. Other generic manufacturers would have entered the market at some point after Barr's 180-day exclusivity period expired, and may have entered as early as the Fourth Quarter of 2005.

108. But for the Defendants' illegal conduct, generic competition would have forced down the price of branded Niaspan, and price competition among the generic suppliers would have been intense.

109. But for the Defendants' illegal conduct, Plaintiff and members of the Class would have paid less for Niaspan. The Defendants' conduct directly injured Plaintiff and the Class by forcing them to pay hundreds of millions of dollars in overcharges on their Niaspan purchases.

110. As a result of the delay in generic competition brought about by the Defendants' overarching anticompetitive scheme, Plaintiff and the Class paid more for Niaspan products than they would have paid absent Defendants' illegal conduct.

111. Barr, Teva and the other ANDA applicants seeking to market generic equivalents to Niaspan had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, manufacturing commercial launch quantities adequate to meet market demand, marketing generic pharmaceutical products, and paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

112. Upon generic entry, generic equivalents of brand-name drugs are priced significantly below the branded drug to which they are AB-rated. As a result, upon generic entry, virtually all branded drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for a generic equivalent of a drug fall even further because of increasing price competition.

113. This price competition enables all end-payors of the drugs to: (a) purchase generic equivalents of the drug at a substantially lower price than the brand; (b) purchase generic equivalents of the drug at a lower price; and/or (c) purchase the brand drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

114. If generic competitors had not been unlawfully prevented from entering the market for earlier and competing with Kos, Abbott and AbbVie, end-payors, such as Plaintiff and members of the Class, would have paid less for Niaspan by (a) substituting purchases of

less-expensive AB-rated generic equivalents Niaspan for their purchases of more-expensive brand Niaspan, and (b) purchasing brand Niaspan at a reduced price.

115. Moreover, due to the Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic equivalents of Niaspan.

116. Thus, the Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

117. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Niaspan indirectly from Kos, Abbott and AbbVie. As a result of Defendants' illegal conduct, members of the Class were compelled to pay artificially inflated prices for their Niaspan requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because Class members were deprived of the opportunity to purchase lower-priced generic equivalents of Niaspan.

118. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

119. Defendants' efforts to restrain competition in the market for Niaspan have substantially affected interstate and foreign commerce.

120. At all material times, Kos, Abbott and AbbVie manufactured, promoted, distributed, and sold substantial amounts of Niaspan in a continuous and uninterrupted flow of

commerce across state and national lines and throughout the United States. The Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic equivalents of Niaspan to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

121. At all material times, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Niaspan.

122. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. Professor Hovenkamp states that “[e]very person at every stage in the chain will be poorer” as a result of the anticompetitive price at the top. Professor Hovenkamp also acknowledges that “[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.”

123. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Niaspan to the Plaintiff and members of the Class.

124. The Defendants' anticompetitive actions enabled Kos, Abbott and AbbVie to indirectly charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the Defendants' unlawful actions.

125. The prices were inflated as a direct and foreseeable result of the Defendants' anticompetitive conduct.

126. The inflated prices that the Class has paid are traceable to, and the foreseeable result of, the overcharges by Kos, Abbott and AbbVie.

IX. CLASS ACTION ALLEGATIONS

127. Plaintiff, on behalf of itself and all Class members, seeks damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for Niaspan.

128. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), as representative of a Class defined as follows:

All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Niaspan, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class"), other than for resale, during the period March 30, 2005 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Niaspan if they paid or reimbursed some or all of the purchase price.

129. The following persons or entities are excluded from the proposed Class:

- a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal government entities, except for government funded employee benefit plans;
- b. All persons or entities who purchased Niaspan for purposes of resale or directly from Defendants or their affiliates;

- c. Fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);
- d. Flat co-payers (*i.e.*, consumers who paid the same co-payment amount for brand and generic drugs); and
- e. The judges in this case and any members of their immediate families.

130. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that there are hundreds of thousands of Class members.

131. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for Niaspan and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Niaspan as a result of the Defendants' wrongful conduct.

132. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

133. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

134. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with

respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

135. Questions of law and fact common to the Class include:

- a. whether Kos, Abbott or AbbVie entered into a contract, combination, and/or conspiracy with Barr or Teva to restrain trade and, if so, whether it should be evaluated under the rule of *per se* illegality, the "rule of reason," or some other rule or standard;
- b. whether Defendants unlawfully excluded competitors and/or potential competitors from the market for Niaspan;
- c. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;
- d. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- e. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Class; and
- f. the quantum of aggregate overcharge damages to the Class.

136. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining

redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in the management of this class action.

137. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

**X. FRAUDULENT CONCEALMENT TOLLING THE
STATUTE OF LIMITATIONS**

138. Plaintiff and members of the Class had no knowledge of Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years prior to the filing of this Complaint.

139. This is so both because the nature of Defendants' conspiracy was self-concealing and because Defendants employed deceptive practices and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme. Notwithstanding the self-concealing nature of their conspiracy, Defendants and their co-conspirators wrongfully and affirmatively concealed the existence of their continuing combination and conspiracy from Plaintiff by, among other things:

- a. Concealing the amounts that Kos was to pay to Barr under the Agreement;
- b. Concealing the fact that those amounts far exceeded any lawful economic benefit that Kos received from Barr under the Agreement;
- c. Issuing a Joint Press Release on April 13, 2005 that claimed that those payments were compensation for Barr promoting Niaspan to obstetricians and gynecologists, and as compensation for Barr agreeing to stand by as a backup supplier, when in fact Kos was paying Barr not to launch a generic equivalent of Niaspan;

- d. In that same Joint Press Release, proclaiming that the Agreement would permit Barr to launch a generic equivalent to Niaspan in 2013, which was supposedly “approximately four years earlier than the last-to-expire Kos patent,” without stating that Kos was going to launch its generic in April of 2005, and without stating that the Agreement delayed generic entry from April of 2005 until September 20, 2013;
- e. Repeating those false and misleading statements about the Agreement in publicly-filed documents (including Kos’ 10-Q filing dated May 10, 2005 at p. 15; Kos’ 10-Q filing dated August 9, 2005, at p. 24; Kos’ 10-Q filing dated November 9, 2005, at p. 25; Kos 10-K filing dated March 10, 2006, at pp. 4, 26; Barr’s 10-Q filing dated May 6, 2005, at pp. 18-19; and Barr’s 10-K filing dated September 13, 2005);
- f. Repeating those same false and misleading statements in the Agreement (including ¶ 4 of the Co-Promotion Agreement; Article 7 of the License and Manufacturing Agreement; and the “Whereas” clauses of the Settlement and License Agreement);
- g. During conference calls with investment bank analysts, refusing to answer direct questions from analysts in the financial community who asked about the financial terms of the payments that Kos was making to Barr (including an April 13, 2005 Conference Call, in which Barr’s Chief Executive Officer Bruce Downey refused to provide details when asked about the financial terms of the Agreement, and including an August 4, 2005 Conference Call, in which Kos’ Interim Chief

Financial Officer Juan Rodriguez refused to provide details of those financial terms); and

- h. Filing redacted versions of the Agreement with the United States Securities and Exchange Commission (Submitted as Exhibits 10.2, 10.3 and 10.4 to Kos' 10-Q filing dated August 9, 2005), so as to conceal the financial terms of the Agreement.

140. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiff and members of the Class had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

141. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting the Plaintiff's and the Class's claims have been tolled.

142. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and the members of the Class can recover for damages that they suffered during the limitations period.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF **For Declaratory and Injunctive Relief** **Under Section 16 of the Clayton Act for** **Defendants' Violations of Section 1 of the Sherman Act** **(Against All Defendants)**

143. Plaintiff incorporates by reference the preceding allegations and paragraphs.

144. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to block and delay entry of competing Niaspan formulations, *i.e.*, AB-rated generic equivalents of Niaspan. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct: (a) to delay Barr and Teva's launch date for the first generic equivalent of Niaspan; (b) to scuttle Kos' launch of an authorized generic equivalent of Niaspan; and (c) to use a bottleneck to delay the launch date of any other generic equivalents of Niaspan. Defendants injured Plaintiff and the Class through an agreement between Kos, Barr, Abbott, Teva and AbbVie to exclude all generic Niaspan products from the market in exchange for (a) cash payments to Barr and Teva, (b) royalties paid to Barr and Teva on the branded Niaspan and Advicor products, and (c) other non-cash considerations paid to Barr and Teva.

145. Defendants' scheme specifically included, *inter alia*, the following events:

- a. On April 12, 2005, Kos and Barr agreed that Kos would pay Barr tens of millions of dollars in exchange for Barr's commitment to delay its launch of a generic equivalent of Niaspan until September 20, 2013.
- b. On April 12, 2005, Kos and Barr agreed that, as part of Kos' payments to Barr, Kos would pay a royalty to Barr on Kos' sales of Advicor, a drug that was not part of any dispute between Kos and Barr.
- c. In April of 2005, Kos abandoned its plans to launch an authorized generic version of Niaspan, Kos destroyed more than \$1.3 million worth of inventory that Kos had accumulated for use in that launch of an authorized generic.

- d. In April of 2005, Barr disposed of, and took write downs on, the inventory that Barr would have used for its generic launch in April of 2005.
- e. In 2005, Kos paid Barr the amounts that were agreed upon as lump-sum payments.
- f. In 2005, and continuing on a quarterly basis thereafter, Kos paid Barr the amounts due for Barr's continuing commitment to delay generic entry until September 20, 2013.
- g. At all times, Barr did in fact delay its generic launch.
- h. When Kos and Barr announced that they had reached they had settled their patent dispute, they made misleading statements that were designed to conceal the unlawful nature of their Agreement.
- i. When Kos was merged into Abbott in 2006, Abbott continued to make the quarterly payments to Barr (and later to Teva) in exchange for the continuing commitment to delay generic launch until September 20, 2013.
- j. In 2008, when Barr was merged into Teva, Teva continued to adhere to the commitment to delay its generic launch until September 20, 2013, and Teva continued to accept quarterly payments from Abbott (and later from AbbVie) as payment for that suppression of generic competition.
- k. When other generic companies filed ANDAs and/or Paragraph IV Certifications seeking permission to launch generic equivalents of Niaspan, Abbott filed patent infringement lawsuits against those companies to block any such generic launch. Abbott then used delay tactics and settlements to ensure that no Court issued a

final judgment regarding Abbott's patents, because Abbott knew that an adverse court ruling on Abbott's patents would have started Teva's 180-day exclusivity period running, and Abbott wanted to be sure that Teva was not forced to launch its generic equivalent of Niaspan before the agreed-upon date of September 20, 2013.

- l. In 2013, when Abbott spun off its pharmaceutical business to AbbVie, AbbVie continued to make payments to Teva, and Teva continued to adhere to its commitment to delay its generic launch until September 20, 2013.
- m. When Teva launches its generic equivalent of Niaspan in September of 2013, Teva will charge a price that is higher than it otherwise would charge for a generic launch, because Teva and AbbVie have agreed to share the profits from Teva's generic launch.

146. Had manufacturers of generic Niaspan products entered the market and lawfully competed with Kos, Abbott, and AbbVie in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic Niaspan products for the higher-priced brand-name Niaspan for some or all of their product requirements, and/or would have paid lower net prices on their remaining Niaspan purchases.

147. Defendants intended, and accomplished, a horizontal market allocation of the Niaspan market, a *per se* violation of Section 1 of the Sherman Act. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on

competition, Plaintiff and members of the Class paid artificially inflated prices for their Niaspan requirements.

148. Plaintiff continues to suffer and will continue to suffer in the future from paying higher prices for Niaspan than it would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreement. Plaintiff and the members of the Class also face a continuing threat of injury from the unlawful conduct alleged in this Complaint.

149. Plaintiff and members of the Class purchased substantial amounts of Niaspan indirectly from Kos, Abbott and AbbVie.

150. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period. And by joining an ongoing unlawful agreement to restrain trade, Abbott and AbbVie are liable for all conduct that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable for their own unlawful conduct.

151. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable for its own unlawful conduct.

152. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Section 1 of the Sherman Act.

153. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the

anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF

**For Conspiracy and Combination in Restraint of Trade Under State Law
(Against All Defendants)**

154. Plaintiff incorporates by reference the preceding allegations and paragraphs.

155. In 2005, Kos and Barr entered into an Agreement to suppress generic competition for Niaspan, and the Agreement has continued as an ongoing agreement since then. Abbott, Teva and AbbVie each joined and continued the unlawful Agreement to suppress generic competition. The Agreement has involved the conduct set forth above. The Agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

- a. Allocate all sales of Niaspan in the United States to Kos, Abbott and AbbVie until September 20, 2013;
- b. Prevent each of the participating companies from selling a generic equivalent or version of Niaspan in the United States until September 20, 2013;
- c. Prevent other generic manufacturers from selling generic equivalents of Niaspan in the United States until 2014;
- d. Fix the price that Plaintiff and members of the Class would pay for Niaspan; and
- e. Fix the price that Plaintiff and members of the Class would pay for generic Niaspan when that product is launched on or after September 20, 2013.

156. The Agreement has harmed Plaintiff and the Class as set forth above.

157. The Agreement has covered a sufficiently substantial percentage of the relevant market to harm competition.

158. The Agreement between Defendants is a horizontal market allocation and price fixing agreement between actual and potential competitors and is illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the Agreement is an unreasonable restraint of trade, in violation of state antitrust law, under a “quick look” or “rule of reason” analysis.

159. There is and was no legitimate, non-pretextual, procompetitive business justification for the Agreement that outweighs its harmful effect. Even if there were such a justification, the Agreement is and was broader than necessary to achieve any conceivable procompetitive purpose.

160. By engaging in the foregoing conduct, Defendants have violated the following state antitrust laws:

- a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Niaspan in Florida by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Iowa Code § 533.12, *et seq.*, with respect to purchases of Niaspan in Iowa by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 740 ILCS § 10/7(2), *et seq.*, with respect to purchases of Niaspan in Illinois by members of the Class.

- d. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Niaspan in Michigan by members of the Class.

161. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Niaspan products, and (2) paying higher prices for Niaspan products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

162. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period, and are liable for all damages that resulted from Kos' unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Abbott and AbbVie are liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable for all damages resulting from their own unlawful conduct.

163. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period, and is liable for all damages that resulted from Barr's unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable for all damages resulting from its own unlawful conduct.

164. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations.

165. The Defendants are jointly and severally liable for all damages suffered by the Plaintiff and the members of the Class.

THIRD CLAIM FOR RELIEF
For Unfair And Deceptive Trade Practices Under State Law
(Against All Defendants)

166. Plaintiff incorporates by reference the preceding allegations and paragraphs.

167. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and Class members were deprived of the opportunity to purchase a generic equivalent of Niaspan and forced to pay higher prices for their Niaspan requirements.

168. There was a gross disparity between the price that Plaintiff and the Class members paid for the brand product and the value received, given that a much cheaper substitute generic product should have been available.

169. By engaging in the foregoing conduct, Defendants have violated the following state unfair and deceptive trade practices and consumer fraud laws:

- a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Niaspan in Florida by members of the Class.

- b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases of Niaspan in Missouri by members of the Class.

170. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Niaspan than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

171. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period, and are liable for all damages that resulted from Kos' unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Abbott and AbbVie are liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable to all damages resulting from their own unlawful conduct.

172. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period, and is liable for all damages that resulted from Barr's unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable to all damages resulting from its own unlawful conduct.

173. To the extent permitted by applicable law, the Defendants are jointly and severally liable for all damages suffered by the Plaintiff and the members of the Class.

FOURTH CLAIM FOR RELIEF
Unjust Enrichment
(Against All Defendants)

174. Plaintiff incorporate by reference the preceding allegations and paragraphs.

175. To the extent required, this Fourth Claim is pled in the alternative from all other Claims in this Complaint.

176. Defendants have benefited from the overcharges on their sales of Niaspan resulting from the unlawful and inequitable acts alleged in this Complaint.

177. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Niaspan by Plaintiff and members of the Class.

178. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and the Class.

179. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiff and the Class.

180. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Niaspan, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Defendants.

181. The economic benefit derived by Defendants through charging supracompetitive and artificially inflated prices for Niaspan is a direct and proximate result of Defendants' unlawful practices.

182. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive prices during the Class Period, inuring to the benefit of Defendants.

183. It would be inequitable under unjust enrichment principles in Florida, Iowa, Illinois, Michigan, and Missouri for the Defendants to be permitted to retain any of the overcharges for Niaspan derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

184. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Class.

185. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds received by them.

186. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

187. Plaintiff and the Class have no adequate remedy at law.

188. As successors in interest to Kos, Abbott and AbbVie are liable for all unlawful conduct committed by Kos during the relevant period, and are liable for all damages that resulted from Kos' unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Abbott and AbbVie are liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that they joined the ongoing unlawful course of conduct. In addition, Abbott and AbbVie are liable to all damages resulting from their own unlawful conduct.

189. As a successor in interest to Barr, Teva is liable for all unlawful conduct committed by Barr during the relevant period, and is liable for all damages that resulted from

Barr's unlawful conduct. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct -- and damages following from all conduct -- that occurred prior to the date that Teva joined the ongoing unlawful course of conduct. In addition, Teva is liable to all damages resulting from its own unlawful conduct.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Class, demands judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare that the Plaintiff is a proper representative of the Class;

B. Declare that the conduct alleged herein is in violation of Section 1 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment in Florida, Iowa, Illinois, Michigan, and Missouri;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiff and the Class;

E. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

April 3, 2013

Respectfully submitted,

/s/ Jeffrey L. Kodroff (JLK4986)

Jeffrey L. Kodroff
SPECTOR ROSEMAN KODROFF & WILLIS PC
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611
jkodroff@srkw-law.com

Kenneth A. Wexler
Amber M. Nesbitt
Justin N. Boley
Catherine Howlett
Thomas A. Doyle, Of Counsel
Kara A. Eggersma, Of Counsel
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Telephone: (312) 346-2222
Fax: (312) 346-0022
kaw@wexlerwallace.com
an@wexlerwallace.com
jnb@wexlerwallace.com
ch@wexlerwallace.com
tad@wexlerwallace.com
kae@wexlerwallace.com

Jonathon D. Karmel
KARMEL LAW FIRM
221 N. La Salle Street, Suite 1307
Chicago, IL 60601
Telephone: (312) 641-2910
Facsimile: (312) 641-0781
jon@karmellawfirm.com

Daniel C. Girard
Dena C. Sharp
Scott M. Grzenczyk
GIRARD GIBBS LLP
601 California Street, 14th Floor
San Francisco, CA 94108
Telephone: (415) 981-4800
Facsimile: (415) 981-4846
dgc@girardgibbs.com
chc@girardgibbs.com
smg@girardgibbs.com

***Counsel For Plaintiff and the
Proposed Class***